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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,152

Applicant(s)

TAJIMA, HIDEJI

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 8-21, 30-35 and 39-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 22-29 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

1. This action is in response to papers filed 8 August 2002 in Paper No. 13 in which claims 1-3, 5, 22-28 and 36-38 were amended and a Terminal Disclaimer was filed. All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action of Paper No. 7 dated 12 March 2002 are withdrawn in view of the amendments and Terminal Disclaimer. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

It is noted that the listing of previously rejected claims on page 6 of Applicant's response incorrectly claims 3-7, 22-29 and 36-38 as rejected. It is assumed by the examiner that this is a typographical error. The previously rejected claims are 1-7, 22-29 and 36-38.

Under the heading "Election/Restriction" on page 6, Applicant states "Due to a previous election made with traverse, claims 8-21, 30-35, 39-49 were deleted without prejudice." It is unclear whether the claims are cancelled by this response or whether Applicant is stating that the claims were previously cancelled or whether Applicant is stating that the claims were withdrawn from consideration. Clarification is requested. For the record, currently claims 1-49 are pending, claims 8-21, 30-35, 39-49 are withdrawn from consideration and claims 1-7, 22-29 and 36-38 are under prosecution.

Specification

2. The amendment filed 8 August 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall

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introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

a. The specification has been amended to insert a first paragraph which cross-references and incorporates by reference the provisional application to which the instant application claims priority. The application, as filed, claimed priority to the provisional application. However, the application, as filed, did not incorporate the provisional application by reference. Therefore, the incorporation by reference constitutes new matter.

b. Claim 1 (from which Claims 2-6 depend) has been amended to recite "said base member is integrated so that a layer surface in which the substances are fixed and are adapted to be formed in the direction of the length of said base member". The specification does not teach or describe the newly claimed "layer surface" and substances "adapted to be formed in the direction of the length of said base member". The specification teaches substances "fixed side by side along the length of the base member" (page 3, lines 26-31). However, the specification does not teach or describe the newly claimed limitations. As such, the amendments to Claim 1 constitute new matter.

c. Independent Claims 1 and 22 have been amended to recite that the substances are fixed... "at intervals" on the base member. The specification does not teach or describe the newly claimed "intervals". In contrast, the specification teaches cavity sections "side by side" (e.g. page 14, lines 4-5). Additionally the specification teaches a base member comprises channels (cavities, apertures) formed at intervals on the base member (e.g. page 33, lines 21-27). However, the specification does not teach or describe the newly claimed substances fixed at intervals. As such, the amendments to Claims 1 and 22 constitute new matter.

d. Claims 37 and 38 have been amended to recite "outside layer surface". The specification does not teach or describe the newly claimed "outside layer surface". The specification teaches a "base member" (e.g. page 3, lines 26-31); integrated medium, cavity section and substrate (e.g. page 33, lines 6-27) but the specification does not teach or describe

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the newly claimed "layer surface". As such, the amendments to Claims 37 and 38 constitute new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

3. Claim 22 is objected to because:
 - a. in line 9, a comma (",") incorrectly precedes and follows "and".
 - b. in line 10, "foam" is incorrectly spelled "form".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 22-29, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Claim 1 (from which Claims 2-7 depend) has been amended to recite "said base member is integrated so that a layer surface in which the substances are fixed and are adapted to be formed in the direction of the length of said base member". The specification does not teach or describe the newly claimed "layer surface" and substances "adapted to be formed in the direction of the length of said base member". The specification teaches substances "fixed side by side along the length of the base member" (page 3, lines 26-31). However, the specification does not teach or describe the newly claimed limitations. As such, the amendments to Claim 1 constitute new matter.

b. Independent Claims 1 and 22 (from which Claims 2-7, 23-29 and 36 depend) have been amended to recite that the substances are fixed... "at intervals" on the base member. The specification does not teach or describe the newly claimed "intervals". In contrast, the specification teaches cavity sections "side by side" (e.g. page 14, lines 4-5). Additionally the specification teaches a base member comprises channels (cavities, apertures) formed at intervals on the base member (e.g. page 33, lines 21-27). However, the specification does not teach or describe the newly claimed substances fixed at intervals. As such, the amendments to Claims 1 and 22 constitute new matter.

c. Claims 37 and 38 have been amended to recite "outside layer surface". The specification does not teach or describe the newly claimed "outside layer surface". The specification teaches a "base member" (e.g. page 3, lines 26-31); integrated medium, cavity section and substrate (e.g. page 33, lines 6-27) but the specification does not teach or describe the newly claimed "layer surface". As such, the amendments to Claims 37 and 38 constitute new matter.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an

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invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. **APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE**" (emphasis added).

35 U.S.C. 112: second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7, 22-29, 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-7 are indefinite in Claim 1 for the recitation "integrated so that a layer surface in which the substances are fixed and are adapted to be formed in the direction of the length of said base member" because the syntax is confusing. Therefore, it is unclear whether the substances are fixed in the direction of the length of the base member or merely adapted to be formed at some future time. It is suggested that Claim 1 be amended to clarify.

b. Claims 5 and 28 are indefinite for the recitation "the auxiliary member" lacks proper antecedent basis in the Claims 5 and 28 respectively because the auxiliary member is present only in the alternative (i.e. and/or auxiliary member). Therefore it is unclear what limitations are being imposed in the absence of the auxiliary member. It is suggested that the claims be amended to clarify.

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c. Claims 22-29 and 36 are indefinite in Claim 22 for the recitation "when the base member is made from a material selected from the group....." because it is unclear whether the recitation modifies all of the base members or merely the last base member listed on line 8. It is suggested that Claim 22 be amended to clarify.

d. Claims 37 and 38 are indefinite in Claim 37 for the recitation "on an outside layer surface" because it is unclear whether the recitation modifies the "conducting measurements" or "optical state". It is suggested that Claim 37 be amended to clarify.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Dehlinger (U.S. Patent No. 5,759,779, issued 2 June 1998).

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Regarding Claim 37, Dehlinger disclose a method of using an integrated medium comprising: a processing step for detecting a substance using an integrated support (i.e. introducing a analyte into the tube array) and a measuring step for conducting measurements of an optical state on an outside layer surface with the integrated support (i.e. measuring the detectable reporter by detecting fluorescence emitted out the end (outer surface) of the capillaries) (Column 11, lines 37-52; Column 3, lines 3-36 and Claims 1-6).

Regarding Claim 38, Dehlinger discloses the method wherein the measuring involves identification of an absolute location on the surface i.e. address-specific position is detected and measured (Column 4, lines 59-62 and Claim 6).

Response to Arguments

10. Applicant argues that Dehlinger only discloses measurement conducted at inner surfaces and therefore does not disclose all elements of Claims 37-38. The argument has been considered but is not found persuasive because as stated above, Claim 37 is indefinite because it is unclear whether the recitation "on an outside layer surface" modifies the measurement or the optical state. For purposes of examination, the recitation is interpreted as modifying either the measurement or optical state. Dehlinger teaches the method wherein fluorescence (optical state) is emitted from the end of the capillaries (outside surface) and measured. The capillary ends of Dehlinger is encompassed by the instantly claimed outside layer surface because they teach the fluorescence is emitted from (and therefore outside) the surface of the capillaries. The measurement of emitted fluorescence of Dehlinger is encompassed by the instantly claimed method because the fluorescence is measured as it is emitted from the end of the capillary and because the fluorescence (which is emitted and therefore outside) is an optical state. Therefore, the measurement of Dehlinger is on an outside surface and the optical state is on an outside surface. As such, Dehlinger discloses the instantly claimed method.

11. Claims 1-6, 22-29 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997).

Regarding Claim 1, Stimpson discloses an integrated support comprising at least one base member, a variety substances for detection of predetermined chemical structure fixed side by side (and at intervals) along the length of the base member wherein said base member is integrated whereby a fixed location of each substance identifies the chemical structure wherein the shape of the base member is selected from a rod shape and a long and slender shape, wherein the means for integration is arranging (a rod member) or rolling (a long and slender member) and wherein each substance is fixed at a location consisting of on the surface of the base member and channels in the base member (Column 3, line 46-Column 5, line 39; Column 12, line 42-Column 13, line 67; and Fig. 2A-E).

Regarding Claim 2, Stimpson discloses the integrated support wherein the material of said base member is selected from a porous material, a fibrous material or an impregnating material (Column 10, lines 16-57 and Column 14, lines 8-10 and 45-48).

Regarding Claim 3, Stimpson discloses the support wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 4, Stimpson discloses the support wherein markings are attached to said base member for identifying the chemical structure (Column 7, lines 49-60 and Column 13, lines 18-20 and 40-41).

Regarding Claim 5, Stimpson discloses the support further comprising a binding section (i.e. adhesive) for binding said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is

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secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 6, Stimpson discloses the support wherein said binding section is an adhesive portion for bonding side portion of said base member (Column 5, lines 48-65).

Regarding Claim 22, Stimpson discloses a method of manufacturing an integrated support comprising a positioning step for positioning and fixing substances for detection at predetermined locations on at least one base member at intervals (Fig. 2) and an integration step for rolling or arranging said base member to give integration so that a surface in which the substances for detection are fixed and the location of the substances for detection is selected from the surface of the base member and in the base member when the base member is made from a porous material (Column 9, lines 18-39; Column 10, lines 16-57; and Column 12, line 56-Column 13, line 59).

Regarding Claim 23, Stimpson discloses the method wherein said base member has a rod shape or a long and slender shape (Column 3, lines 36-46).

Regarding Claim 24, Stimpson discloses the method wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member (Column 7, lines 19-28 and Column 9, lines 18-42).

Regarding Claim 25, Stimpson discloses the method wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 26, Stimpson discloses the method wherein said base member is formed as a thin sheet said substances for detection are positioned on the base member in lines which do not intersect or contact each other and said integration step involves rolling in a way that either prevents or enables expansion (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C) and wherein a cutting step is provided following integration in which the base member

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is sliced thinly to form a plurality of integrated supports in which the cross-sectional surface functions as a layer surface (Column 6, line 64-Column 7, line 6; Column 9, lines 8-17; Column 12, lines 65-67; Column 13, lines 26-31 and 60-61 and Fig. 2).

Regarding Claim 27, Stimpson discloses the method wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member (Column 7, lines 19-28 and Column 9, lines 18-42) wherein said base member is made from a porous material, a fibrous material or an impregnating material (Column 9, lines 18-39 and Column 10, lines 16-57).

Regarding Claim 28, Stimpson discloses the method wherein in the integrating step, said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 29, Stimpson discloses the method wherein in the positioning step said substances are fixed and supported onto said base member by drying i.e. placed on paper towel (Example 6, Column 16, lines 18-23).

Regarding Claim 36, Stimpson discloses a method of using the integrated medium of Claim 22 wherein passing a heating fluid (sample) through the integrated support, the integrated support is heated (Example 5, Column 15, line 37-Column 16, line 13).

Regarding Claim 37, Stimpson discloses a method of using an integrated medium comprising: a processing step for detecting a substance using an integrated support and a measuring step for conducting measurements of an optical state on an outside layer surface with the integrated support (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claims 10-11).

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Regarding Claim 38, Stimpson discloses the method wherein the measuring involves identification of an absolute location on the surface i.e. address-specific position is detected and measured (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claim 10 (e)).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997) in view of Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 7, Stimpson teaches an integrated support comprising at least one base member, a variety substances for detection of predetermined chemical structure fixed side by side (and at intervals) along the length of the base member wherein said base member is integrated whereby a fixed location of each substance identifies the chemical structure wherein the shape of the base member is selected from a rod shape and a long and slender shape, wherein the means for integration is arranging (a rod member) or rolling (a long and slender member) and wherein each substance is fixed at a location consisting of on the surface of the base member and channels in the base member (Column 3, line 46-Column 5, line 39; Column 12, line 42-Column 13, line 67; and Fig. 2A-E) wherein the integrated support comprises a linear member (cylindrical support) embedded inside the base member (Column 6, lines 59-63

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and Fig. 2 #240) and Stimpson teaches that the support is exposed to fluids of differing temperatures (Example 5, Column 15, line 37-Column 16, line 13) but Stimpson is silent regarding the thermal properties (i.e. homoiothermal) of the embedded member. Lipshutz teaches a similar integrated support comprising a rod shaped and/or long and slender shaped base member (i.e. capillaries Column 11, lines 59-64) and a variety of substances fixed side by side along the length of said base member wherein said base member is arranged to give integration and wherein a thermal member is embedded inside said base member for controlling and maintaining uniform temperature within integrated support (Column 19, lines 1-4) wherein the thermal member is linear (Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the integrated support of Stimpson by embedding a thermal member for maintaining a uniform temperature as taught Lipshutz et al (Column 19, lines 1-4) and as instantly claimed. The thermal member of Lipshutz et al would permit the integrated support used to control and maintain appropriate temperatures while utilizing the integrated support of Stimpson. Therefore, one of ordinary skill would have been motivated to integrate the thermal member of Lipshutz et al into the integrated support of Stimpson for the expected benefits of controlling and maintaining desired temperatures in hybridization applications of Stimpson (Examples 5-6, Column 15, line 37-Column 16, line 30)

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
February 25, 2003